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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,386	02/10/2004	Stephen F. Badylak	3220-74469	9910

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BARNES & THORNBURG LLP
11 SOUTH MERIDIAN
INDIANAPOLIS, IN 46204

EXAMINER	
FORD, ALLISON M	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/775,386	BADYLAK, STEPHEN F.	
	Examiner	Art Unit	
	Allison M. Ford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *17-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 17-21, drawn to a composition comprising gelled liver basement membrane tissue, nutrients and cells, classified in class 435, subclass 397.

II. Claims 20-23, drawn to a composition comprising culture-ware coated with gelled liver basement membrane tissue and nutrients, classified in class 424, subclass 553.

III. Claims 24-27, drawn to a method for inducing tissue formation *in vivo*, classified in class 424, subclass 422.

IV. Claims 28-34, drawn to a method for preparing a tissue graft composition, classified in class 435, subclass 378.

The inventions are distinct, each from the other because of the following reasons:

Claim 20 links inventions I and II. Claim 20 is directed to a composition comprising (i) gelled liver basement membrane tissue of a warm-blooded vertebrate, and (ii) added nutrients; this composition is included in each of the compositions of claims 17-19 and claims 22-23, yet the compositions of claims 17-19 and claims 22-23 each contain additional elements that render the compositions patentably distinct from one another. Specifically, the composition of claims 17-19 further requires cells, which is not included in the composition of claims 22-23; alternatively the composition of claims 22-23 further requires culture-ware, and require the gelled liver basement membrane tissue to be coated on the culture ware, which is not required in the composition of claims 17-19. Therefore, linking claim 20, and dependent claim 21, are included in both Group I (claims 17-19 + 20-21) and Group II (claims 22-23 + 20-21) for examination.

The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim, claim 20. Upon the indication of allowability of the subject matter of claim 20, the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

As discussed above, the inventions of Groups I and II are directed to related products/compositions. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions of Groups I and II are considered distinct because they each have materially different components that render the compositions patentably distinct. For example, the composition of Group I requires cells, wherein cells are not required in the composition of Group II; alternatively the composition of Group II requires culture-ware, and further requires the culture-ware to be coated with the gelled liver basement membrane tissue, the composition of Group I neither requires culture-ware, nor does it require the gelled liver

basement membrane tissue to be in the form of a coating, rather it allows for the gelled liver basement membrane tissue to retain a natural 3-D shape/configuration.

The inventions of Groups I, II and III are directed to unrelated products and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the method of Group III requires implantation of a composition comprising gelled liver basement membrane tissue, it is noted that while both compositions of Groups I and II comprise gelled liver basement membrane tissue, the compositions of Groups I and II further require additional elements that appear to render them inappropriate for use in the method of Group III.

Regarding the composition of Group I, the composition of Group I further requires cells, the method of Group III does not require the implanted graft to comprise cells that have been added *ex vivo*, but rather intends for endogenous cells to infiltrate the graft composition *in vivo*. However, even if one were to argue the composition of Group I can be used in the method of Group III, the product and process would still be patentably distinct because the product composition of Group I could be used in materially distinct methods, such as for *in vitro* testing and diagnostics or as an *in vitro* cell scaffold for developing artificial tissues; such methods and uses of the composition of Group I *in vitro* are distinct from the implantation method of Group III.

Regarding the composition of Group II, the composition of Group II requires culture-ware coated with the gelled liver basement membrane tissue, culture-ware is not appropriate for implantation *in vivo*, as is required by the method of Group III, rather use of culture-ware is limited to use *in vitro*. Therefore, the composition of Group II cannot be used in the method of Group III and thus the inventions are unrelated and distinct.

The inventions of Groups I, II and IV are also directed to unrelated products and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the method of Group IV is directed to a method for producing a tissue graft composition, wherein the method comprises treating liver tissue with a cell dissociation solution, separating the cellular components from the remaining extracellular components, and then digesting the extracellular components and adding nutrients to form a fluidized liver basement membrane tissue. Such a method is not sufficient to make either of the compositions of Groups I or II.

Regarding the composition of Group I, the composition of Group I requires cells, the method of Group IV requires all cells to be removed from the tissue source, and does not include an additional step of adding additional cells back to the final composition; thus the method of Group IV would not result in the composition of Group I.

Regarding the composition of Group II, the composition of Group II requires culture-ware to be coated with the liver tissue basement membrane tissue; the method of Group IV does not involve steps that provide or coat culture-ware with the final composition; thus the method of Group IV would not result in the composition of Group II.

Finally, the inventions of Groups III and IV directed to distinct methods. The inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed do not comprise overlapping or co-extensive method steps, and neither method is required for the practice of the other. For example, the method of Group III requires an implantation step, the method of Group IV does not require implantation, but alternatively produces a

composition that could be used *ex vivo* or *in vitro*. The method of Group IV requires steps of decellularizing liver tissue, the method of Group III does not require a decellularization step, it, in fact, does not require the tissue for implantation to be acellular, but rather could involve implantation of a tissue that includes cells.

Therefore, a search and examination of all inventions in one patent application would result in an undue burden. These inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classifications, and a search for one group does not require a search for another group, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, which ever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and

process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in the light of *In re Ochiai, In re Brouwer* and 34 U.S.C § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leon B Lankford, Jr
Primary Examiner
Art Unit 1651